# UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	) ) )	MDL No. 1:13-md-2419-RWZ
This Document Relates to: All Cases	) ) )	

# JOINT STATUS REPORT OF THE CHAPTER 11 TRUSTEE AND THE OFFICIAL COMMITTEE OF UNSECURED CREDITORS

### **DUANE MORRIS LLP**

Michael R. Gottfried, Esq. 100 High Street Suite 2400 Boston, MA 02110-1724 Telephone: (857) 488-4200 mrgottfried@duanemorris.com

Counsel for Paul D. Moore, Chapter 11 Trustee of New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center

and

## HARRIS BEACH PLLC

Frederick H. Fern, Esq. 100 Wall Street New York, NY 10005 Telephone: (212) 687-0100 hbnecc@harrisbeach.com

Specially Appointed Counsel to the Chapter 11 Trustee of New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center

#### **BROWN RUDNICK LLP**

David J. Molton, Esq. Seven Times Square New York, New York 10036 Telephone: (212) 209-4800 Facsimile: (212) 209-4801 dmolton@brownrudnick.com

and

William R. Baldiga, Esq. Kiersten A. Taylor, Esq. One Financial Center Boston, Massachusetts 02111 Telephone: (617) 856-8200 Facsimile: (617) 856-8201 wbaldiga@brownrudnick.com ktaylor@brownrudnick.com

Counsel to the Official Committee of Unsecured Creditors of New England Compounding Pharmacy, Inc. Paul D. Moore, the Chapter 11 Trustee (the "<u>Trustee</u>") for the bankruptcy estate of New England Compounding Pharmacy, Inc. ("<u>NECC</u>" or the "<u>Debtor</u>"), and the Official Committee of Unsecured Creditors (the "<u>Committee</u>") appointed in NECC's Chapter 11 case (the "<u>Chapter 11 Case</u>"), by and through their undersigned counsel, respectfully submit this joint status report (this "<u>Report</u>") for the purpose of providing this Court with a report concerning the progress and status of this multi-district litigation proceedings (the "<u>MDL Proceeding</u>") and NECC's Chapter 11 Case.

## **INTRODUCTION**

- 1. As described in more detail below, NECC compounded and dispensed methylprednisolone acetate ("MPA"), an injectable steroid that has allegedly caused personal injury and death to patients who received injections containing MPA from, *inter alia*, pain clinics and medical providers who purchased MPA from NECC. The subsequent shutdown of operations and the magnitude of the personal injury claims against NECC resulted in the company filing for relief under Chapter 11 of Title 11 of the United States Code (the "Bankruptcy Code") on December, 21, 2012.
- 2. On January 18, 2013, the Office of the United States Trustee (the "<u>UST</u>"), pursuant to Bankruptcy Code Section 1102(a)(1), appointed the nine (9) member Committee, eight (8) of whom are tort claimants holding personal injury tort and/or wrongful death claims against the Debtor and others [Bankr. Dkt. No. 67]. The eight tort claimants' attorneys serve as their representatives on the Committee.<sup>1</sup> The co-chairs of the Committee are Anne Andrews of

The members of the Committee include: (i) Katrina Eldreth (represented by Anne Andrews of Andrews & Thornton); (ii) Meghan A. Handy (represented by Harry M. Roth and Michael Coren of Cohen Placitella & Roth P.C.); (iii) Robert Cole (represented by Thomas Sobol and Kristen Johnson Parker of Hagens Berman Sobol Shapiro LLP); (iv) Brenda Bansale (represented by Marc Lipton of Lipton Law); (v) Victor Davis (represented by Terry Dawes of Fieger, Fieger, Kenney, Giroux & Danzig, P.C.); (vi) Kathleen Distler (represented by Melvin Wright of Colling Gilbert Wright & Carter, LLC); (vii) Danny Swartzell (represented by Greg Skikos of Skikos Crawford Skikos); (viii) Bertram Walker Bryant, Jr. (represented by

Andrews & Thornton, located in Irvine, California, and Harry M. Roth and Michael Coren of Cohen Placitella & Roth P.C, located in Philadelphia, Pennsylvania.

- 3. On January 25, 2013, Paul D. Moore was appointed as the Chapter 11 Trustee of the Debtor's estate.
- 4. Three hundred and twenty-one (321) lawsuits resulting from the outbreak have been consolidated in this multi-district litigation.<sup>2</sup>
- 5. To date, the Trustee and the Committee, working with the Plaintiffs' Steering Committee appointed in this MDL Proceeding (the "PSC"),<sup>3</sup> have made significant progress toward substantial settlements to be implemented in and effectuated by a Chapter 11 plan (the "Plan") in the Chapter 11 Case that will seek to resolve:
  - all of the claims of those individuals exposed to NECC's MPA against NECC
     and NECC's insiders and affiliated companies, and
  - ii) many of these tort claimants' claims against other entities and individuals alleged to be responsible for the injuries incurred.

The Trustee and the Committee expect to present the Plan for confirmation to the Honorable Henry J. Boroff of the Bankruptcy Court for the District of Massachusetts (Eastern Division) (the "Bankruptcy Court") within this calendar year.

Michael D. Galligan of Galligan Newman Law); and (ix) NStar Electric Company (the non-tort claimant member, represented by Honor Heath).

Attached hereto as **Exhibit A** is a schedule of lawsuits consolidated in this MDL Proceeding, organized by plaintiff last name, docket number, and court of origin.

The members of the PSC include: (i) Thomas M. Sobol and Kristin Johnson Parker of Hagens Berman Sobol Sharpiro LLP; (ii) Mark P. Chalos of Lieff Babraser Heimann & Bernstein, LLP; (iii) Marc Lipton of Lipton Law; (iv) Kim Dougherty of Janet, Jenner & Suggs, LLC; (v) Patrick T. Fennell of Crandall & Katt; (vi) J. Gerard Stranch, IV of Bransetter, Stranch & Jennings PLLC; and (vi) Mark Zamora of the Zamora Firm. In addition to their service on the PSC, Mr. Sobol, Ms. Johnson Parker, and Mr. Lipton also serve as member representatives on the Committee.

6. The Trustee has described the Plan as follows:

[P]otentially liable parties, including the allegedly culpable insiders of the Debtor, would contribute funds in amounts to be negotiated into a common fund. To ensure finality, and to induce potentially liable parties to contribute to the fund, the Trustee contemplates the Chapter 11 plan would provide third party releases to those potentially liable parties who make the substantial contributions the Trustee envisions will be required by such parties.<sup>4</sup>

- 7. On December 23, 2013, there was substantial progress toward the Plan with the joint announcement by the Trustee and the Committee that preliminary settlements had been reached with NECC's owners, insurers, and affiliated companies, who together are to contribute an amount estimated to be in excess of \$100 million to a common fund for distribution to NECC's creditors, including tort claimants, through the Plan. Mediations with other potentially liable defendants are in progress with the assistance of Professor Eric Green and Carmin Reiss, Esquire of Resolutions LLC.
- 8. Given the length and complexity of the Chapter 11 Case and the MDL Proceeding, and the substantial progress made over the past twelve months (as recited below), the objective of this Report is to provide this Court with a brief history and present posture of

See Joint Motion of Plaintiff Paul D. Moore as He is Trustee of the Chapter 11 Estate of New England Compounding Pharmacy, Inc., Defendants, Barry Cadden, Lisa Conigliaro Cadden, Gregory Conigliaro, Carla Conigliaro and Reach-And-Apply Defendants, Ameridose LLC, GDC Properties Management, LLC and Medical Sales Management for Approval and Entry of Agreed-Upon Order Establishing Protocol for Settlement Negotiations and Communications ¶ 20 [Adv. Pro. Dkt. No. 89] (the adversary proceeding currently being prosecuted by the Trustee against certain shareholders and affiliates of NECC is described in detail in section I.C, infra); see also Memorandum of Law in Support of Chapter 11 Trustee's Motion to Transfer Personal Injury Tort and Wrongful Death Cases to This Court Pursuant to 28 U.S.C. § 157(b)(5) and 1334, 2-3 [MDL Dkt. No. 38].

The type of plan envisioned by the Trustee and the Committee has been successfully formulated, negotiated and confirmed, providing substantial recoveries (aggregating several hundreds of millions of dollars) to claimants, in the following tort-related bankruptcies: <u>TL Admin. Corp. et al. f/k/a TwinLab Corp., et al.</u> [Case No. 03-15564, Bankr. S.D.N.Y., Drain, J. (reference partially withdrawn to S.D.N.Y., Rakoff, J.]; <u>In re N.V.E., Inc.</u> [Case No. 05-35692, Bankr. D.N.J., Winfield, J.]; <u>In re Muscletech Research & Dev., Inc.</u> [Case No. 06-cv-00538, S.D.N.Y., Rakoff, J.]; and <u>In re MII Liquidation Inc.</u> [05-06040, Bankr. S.D. Cal., Hargrove, J.]. In connection with these bankruptcies, District Judge Rakoff of the Southern District of New York also administered the multi-district proceedings to which these bankruptcies were related. <u>In re Ephedra Products Liability Litigation</u> [Case No. 04 M.D. 1598, S.D.N.Y., Rakoff, J.].

these proceedings, and more specifically of the progress towards the formulation and consummation of a Plan that will benefit the tort claimants, as well as the other creditors of NECC.<sup>5</sup>

9. For the Court's convenience, a simplified timeline outlining the major case events described in this Report is attached hereto as **Exhibit B**. The Trustee and his counsel, as well as the Committee and its counsel, are available to answer any questions or address any concerns this Court may have with respect to the issues.

## **STATUS REPORT**

# I. <u>BACKGROUND</u>

# A. <u>NECC's Prepetition Operations</u>

10. NECC is a Massachusetts corporation with its principal place of business at 697 Waverly Street, Framingham, MA 01702. Prior to the Chapter 11 Case's Petition Date (as defined herein), NECC operated as a compounding pharmacy which combined and mixed active and inactive ingredients to create formulations of compounded pharmaceutical products. Beginning in September 2012, reports began to surface of several patients diagnosed with a rare strain of fungal meningitis (the "Outbreak") after receiving injections of preservative-free MPA compounded by NECC.<sup>6</sup>

On a parallel track to the Trustee's and the Committee's efforts, and typically in conjunction with the Trustee and the Committee, the PSC has been directing the progress of litigation on behalf of individual plaintiffs in the MDL Proceeding, against parties alleged to be responsible for the plaintiffs' injuries, including pain clinics and health care providers that administered the tainted NECC drug to patients (all plaintiff litigation against NECC is, of course, stayed by Chapter 11 Case's automatic stay pursuant to 11 U.S.C. § 362). This Report will not directly address the discrete litigation proceedings in this Court, other than to identify those matters and proceedings that concern the Trustee's and Committee's efforts in connection with the Plan. The Trustee and the Committee expect that the PSC will be submitting a report, orally or in writing, to advise this Court of their progress in the ongoing MDL litigation.

MPA is used to treat swelling and pain in the spine and joints associated with arthritis and other orthopedic disorders. Healthcare professionals administer MPA by injecting it into the affected location, often epidurally.

- 11. On October 1, 2012, the Massachusetts Department of Public Health (the "MDPH") issued a formal quarantine order pursuant to M.G.L. ch. 94C, §§ 13 & 189A, and M.G.L. ch. 112, §§ 30 & 42A, requiring NECC to preserve all products used to compound MPA, including products returned from pharmacies. After an initial recall of the three suspect MPA lots on September 26, 2012, NECC undertook further recalls on October 3, 2012 of all intrathecal products (for injection into the spinal cord or brain); on October 4, 2012 of all injectable medications; and on October 6, 2012 of all NECC-compounded medications dispensed since January 1, 2012. In response to October 2, 2012 findings from the United States Food and Drug Administration and the MDPH, the Massachusetts Board of Registration in Pharmacy requested a voluntary surrender of NECC's pharmacy license. NECC surrendered its license on October 3, 2012.
- 12. The Outbreak has resulted in hundreds of personal injury and wrongful death claims against NECC and others. The Centers for Disease Control and Prevention ("CDC") reports that, as of October 23, 2013, 64 people had died and 751 individuals had fallen ill. NECC has surrendered its pharmacy license, suspended operations, and terminated its employees. The MDPH also has temporarily barred three former NECC pharmacists from practicing pharmacy.

# B. Commencement of the Chapter 11 Case and the MDL Proceeding

- 13. On December 21, 2012 (the "<u>Petition Date</u>"), NECC filed a voluntary petition for relief under Chapter 11 of the Bankruptcy Code.
  - 14. On January 18, 2013, the UST appointed the Committee.

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Reported at http://www.cdc.gov/HAI/outbreaks/meningitis-map-large.html#casecount\_table (last visited on February 24, 2014). The CDC has not updated the case counts since October 23, 2013 and indicates that further updates to the case counts are not anticipated.

- 15. On January 25, 2013, the Bankruptcy Court granted the UST's *Certificate of Appointment* appointing the Trustee.
- 16. On February 12, 2013, the Judicial Panel on Multidistrict Litigation entered an order establishing this multidistrict litigation and transferring actions against NECC involving the contaminated MPA (which were commenced prior to the filing of NECC's bankruptcy petition), as well as all actions against its affiliates, to this Court for consolidated pretrial proceedings.
- 17. On April 9, 2013, this Court entered an order establishing the seven-attorney PSC to organize, simplify, and streamline the handling of the MDL Proceeding on behalf of all plaintiffs to actions therein. <u>See MDL Order No. 2 [MDL Dkt. No. 83].</u>

# C. <u>Claims and Proceedings by the Committee, the Trustee, and Third Parties</u> <u>Against NECC's Officers, Shareholders, and Affiliates; Stay of Discovery</u>

18. On January 24, 2013, prior to the Trustee's appointment, the Committee, on behalf of NECC's bankruptcy estate, commenced Adversary Proceeding No. 13-01040 in the Bankruptcy Court (the "Adversary Proceeding") against Barry J. Cadden, Lisa Conigliaro Cadden, Gregory Conigliaro, Carla Conigliaro, Ameridose, LLC, GDC Properties Management, LLC, and Medical Sales Management, Inc. (collectively, the "NECC Affiliated Defendants"). In its Complaint, the Committee sought to avoid as preferential and constructively fraudulent transfers over \$20 million in pre-petition transfers made to or for the benefit of the NECC Affiliated Defendants during the twelve months prior to NECC's bankruptcy filing. The Committee also sought to disallow claims that the NECC Affiliated Defendants may assert against NECC, and to recover damages due to alleged breaches by the Caddens and Conigliaros

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One or more of the individual NECC Affiliated Defendants own all of the equity interests in NECC, Ameridose, LLC, Medical Sales Management and GDC Properties Management, LLC.

of fiduciary duties of loyalty and care owed to NECC in their capacity as directors of NECC.

- 19. On the same day *i.e.*, January 24, 2013 the Committee filed in the Adversary Proceeding an Emergency Motion for Temporary Restraining Order and Preliminary Injunctive Relief [Adv. Pro. Dkt. No. 3] (the "TRO/PI Motion"), Emergency Motion for Attachment on Trustee Process [Adv. Pro. Dkt. No. 5] (the "Trustee Process Motion"), Emergency Motion for Reach and Apply Injunction [Adv. Pro. Dkt. No. 6] (the "Reach and Apply Motion"), and Emergency Motion for Approval of Real Estate Attachment [Adv. Pro. Dkt. No. 9] (the "Real Estate Attachment Motion").
- 20. After a hearing on January 25, 2013, the Bankruptcy Court issued, on January 28, 2013, the following orders with respect to the Committee's motions:
  - (i) an order partially granting the TRO/PI Motion, and temporarily restraining and enjoining Barry Cadden, Lisa Conigliaro Cadden, Gregory Conigliaro, and Carla Conigliaro (the "NECC Shareholder Defendants") from transferring, encumbering, assigning, pledging, mortgaging, or spending any asset other than as necessary for ordinary living or legal-representation expenses, except by leave of the Bankruptcy Court [Adv. Pro. Dkt. No. 22] (the "TRO Order");
  - (ii) an order granting the Trustee Process Motion, and ordering the attachment of up to \$21,110,344.30 on each of six bank accounts held for the benefit of the Shareholder Defendants [Adv. Pro. Dkt. No. 20];
  - (iii) an order granting the Reach and Apply Motion, and restraining and enjoining Ameridose LLC, GDC Properties Management, LLC, and Medical Sales Management, Inc. from paying, transferring, distributing, disbursing, or in any way alienating any amounts due or to become due to the NECC Shareholder Defendants [Adv. Pro. Dkt. No. 19]; and
  - (iv) an order granting the Real Estate Attachment Motion, and ordering the attachment of up to \$21,110,344.30 on each piece of real property standing in the name of the NECC Shareholder Defendants in the Commonwealth of Massachusetts [Adv. Pro. Dkt. No. 21].
- 21. On February 12, 2013, following the Trustee's appointment, the Bankruptcy Court entered a Stipulated Order, agreed to by the Trustee, the Committee and the NECC

Affiliated Defendants (the "<u>February 2013 Stipulation</u>"), whereby the TRO Order matured into a preliminary injunction and the Trustee was substituted for the Committee as the plaintiff in the Adversary Proceeding.

22. In addition to the claims asserted in the Adversary Proceeding, numerous plaintiffs allege that the NECC Affiliated Defendants are liable to them for personal injury tort and wrongful death based on various alleged acts and omissions that resulted in the contamination of NECC's products that caused the Outbreak. The theories of liability are varied, but, at bottom, the NECC Affiliated Defendants are alleged to have caused the Outbreak, or been complicit with those who caused the Outbreak that resulted in their civil liability. Moreover, there are also at least two ongoing federal and state criminal investigations in which one or more of the NECC Affiliated Defendants may be targets.

## D. The Bar Date and Proofs of Claim in the Chapter 11 Case

23. The automatic stay that arose as of the filing of the Chapter 11 Case precluded the commencement or continuation of any litigation against NECC. Seeking to establish a deadline for filing proofs of claim against NECC, in early July, 2013, the Trustee submitted the Chapter 11 Trustee's Motion for an Order (I) Establishing Bar Dates for Filing Proofs of Claim; (II) Approving Certain Additional Documentation Requirements and Procedures for Personal Injury Tort and Wrongful Death Claims; (III) Approving the Form and Manner of Notice Thereof; and (IV) Granting Additional Related Relief [Bankr. Dkt. No. 263] and the Supplemental Statement Regarding Chapter 11 Trustee's Motion for an Order (I) Establishing Bar Dates for Filing Proofs of Claim; (II) Approving Certain Additional Documentation Requirements and Procedures for Personal Injury Tort and Wrongful Death Claims; (III) Approving the Form and Manner of Notice and Manner of Notice Thereof; and (IV) Granting Additional Relief [Bankr. Dkt. No. 269] (collectively, the "Bar Date Motion"). The Committee supported the Bar Date

Motion. See, e.g., Statement Of The Official Committee Of Unsecured Creditors In Support Of The Chapter 11 Trustee's Motion For An Order (I) Establishing Bar Dates For Filing Proofs Of Claim; (II) Approving Certain Additional Documentation Requirements And Procedures For Personal Injury Tort And Wrongful Death Claims; (III) Approving The Form And Manner Of Notice Thereof; And (IV) Granting Related Relief [Bankr. Dkt. No. 346]. The PSC filed an opposition to certain aspects of the Bar Date Motion. [Bankr. Dkt. No. 365].

- 24. On July 24, 2013, the Bankruptcy Court held a hearing on the Bar Date Motion (the "Bar Date Hearing") and immediately thereafter entered an interim order on the Bar Date Motion. See Interim Order Regarding Chapter 11 Trustee's Motion for an Order Establishing Bar Dates for Filing Proofs of Claim and for Related Relief Concerning Notice by Notice Intermediaries [Bankr. Dkt. No. 412] (the "Interim Bar Date Order"). The Interim Bar Date Order required that each of the "NECC Contaminated Product Recipients" (i.e., the pain clinics and medical care providers who purchased the MPA and administered it to the tort claimants) prepare a list (each, a "List") containing, the name of each person to whom that particular recipient administered MPA (the "Potential Claimants"), together with the following information:
  - i) Name:
  - ii) Address, telephone number and e-mail address;
  - iii) Last four digits of such individual's social security number;
  - iv) Product(s) from the Lots that was (were) administered (including the Lot number(s) of the Lot(s) in which such product(s) was (were) included);
  - v) The date(s) on which such product(s) was (were) administered; and
  - vi) the identity of the facility and the person or persons who administered such product(s).

<u>See</u> Interim Bar Date Order ¶ 1. Each NECC Contaminated Product Recipient was required to submit its List to the Trustee, counsel to the Official Committee, and Lead Counsel to the PSC by August 16, 2013. See Interim Bar Date Order ¶ 2.

- 25. After extensive "back and forth" with certain NECC Contaminated Product Recipients, including appeals of and motions to reconsider the Interim Bar Date Order by certain NECC Contaminated Product Recipients, on one hand, and joint motions by the Trustee and the Committee to hold non-compliant NECC Contaminated Product Recipients in contempt of the Interim Bar Date Order, on the other hand, each NECC Contaminated Product Recipient eventually submitted its List. The Lists have assisted the Trustee, counsel to the Official Committee and Lead Counsel to the PSC in assessing the number of potential claims against the NECC estate.
- 26. On September 27, 2013, the Bankruptcy Court entered a final order on the Bar Date Motion, establishing January 15, 2014 as the date by which all proofs of claim were to be filed against NECC in the Chapter 11 Case and ordering the Trustee to serve the proof of claim form and other claim papers (collectively, the "Bar Date Package") by first-class mail on, among others, all persons identified in the Lists. See Order (I) Establishing Deadline for Submitting Proofs of Claim, (II) Approving Certain Additional Requirements and Procedures for Personal Injury Tort and Wrongful Death Claims and (III) Approving Form and Manner of Notice Thereof [Bankr Dkt. No. 582] (the "Bar Date Order", attached hereto as Exhibit C).9

The Trustee undertook significant and thorough efforts to obtain the names and addresses of all Potential Claimants pursuant to the Interim Bar Date Order, including through use of the Lists, and to provide direct notice by mail of the January 15, 2014 bar date to approximately twenty thousand (20,000) known creditors and potential tort claimants in the Chapter 11 Case in accordance with the Bar Date Order. The Trustee also published notice of the bar date in more than sixty (60) publications throughout the country on two separate occasions in an effort to notify any remaining unknown individuals who may have been impacted by tainted NECC products.

Recently, the Trustee learned that certain Potential Claimants were omitted from this service. Due to an oversight, the Debtor's claims and noticing agent ("Donlin Recano") did not serve the Bar Date Package

- 27. The Bar Date Order requires, *inter alia*, that creditors asserting a personal injury tort or wrongful death claim against NECC arising from exposure to NECC products ("<u>PITWD</u> <u>Claimants</u>") submit an addendum with their proofs of claim (the "<u>PITWD Addendum</u>"). The PITWD Addendum requests additional information from each PITWD Claimant related to his or her claim, including, *inter alia*:
  - i) Case information type of injury sustained as a result of exposure to the NECC product; case information for any civil actions filed against NECC, any affiliated entity or individual or any hospital, clinic, physician, NECC related company, principal or distributor;
  - ii) Personal information address, date of birth, marital status;
  - iii) Medical information date of injection; product information (name, dosage, amount, lot number); name of hospital, clinic or physician's office where patient was injected; diagnosis and test results; information regarding notification of potential exposure; treatment information; prescriptions;
  - iv) Information related to medical expenses health insurance information, medical bills; and
  - v) Employment information.
- 28. As of February 26, 2014, over 3,600 individuals or entities had filed proofs of claims against NECC. Approximately 3,360 individuals submitted a PITWD Addendum alleging personal injury or wrongful deaths resulting from the administration of NECC products.

upon Potential Claimants from three of the clinics that had provided Lists to the Trustee to facilitate notification of the bar date (collectively, the "Affected Claimants"). Accordingly, on February 24, 2014, the Trustee filed, with the consent of the Committee, the Office of the United States Trustee and the PSC, the Chapter 11 Trustee's Assented-To Motion for Entry of a Supplemental Order Establishing a Bar Date for Filing Proofs of Claim and Request to Limit Notice [Bankr. Dkt. No. 679], seeking entry of an order (a) authorizing him to direct Donlin Recano to serve the affected claimants with the Bar Date Package and (b) establishing an extended bar date, 60 days after service of the Bar Date Package, for those potential creditors that may not previously have received direct notice by mail of the bar date. On February 24, 2014, the Bankruptcy Court entered an order extending the bar date for the Affected Claimants to May 5, 2014. [Bankr. Dkt. No. 699].

# II. CASE DEVELOPMENTS TOWARDS RESOLUTION AND A PLAN

29. As described above, the Trustee and the Committee envision a resolution, to be embodied in the Plan, of the claims resulting from the Outbreak against NECC, its insiders and affiliates, and other non-affiliated parties. To date, significant progress has been made.

## A. Settlement with NECC's Insiders

- 30. A crucial centerpiece of the Plan envisioned by the Trustee and the Committee is to obtain significant contributions from the NECC Affiliated Defendants and related parties (collectively, the "<u>Insiders</u>") to the NECC estate for delivery to a "<u>Claimants' Compensation Fund</u>", for distribution through the Plan, to benefit the PITWD Claimants. Accordingly, since the Petition Date and the UST's appointments of the Committee and the Trustee, the Trustee and the Committee have viewed settlement negotiations with the Insiders as among their highest priorities.
- 31. To establish protocols to maintain the confidentiality of information disclosed in the context of settlement negotiations with the Insiders, on April 18, 2013, the Bankruptcy Court entered an *Agreed-Upon Order Establishing Protocol for Settlement Negotiations and Communication* [Adv. Pro. Dkt. No. 96, as amended by Adv. Pro. Dkt. No. 99] (the "Protocol Order", attached hereto as **Exhibit D**). In aid of the Protocol Order and the Trustee's settlement negotiations, this Court stayed all formal discovery against the Insiders that were consolidated into the MDL Proceeding, <sup>10</sup> and ordered that the discovery stay continue pending a further order. See Clerk's Notes for Mar. 12, 2013 Status Conference (extending discovery stay to Apr. 10, 2013); Tr. of Apr. 10, 2013 Status Conference at 28:17-24 (extending discovery stay to May 14,

On April 19, 2013, discovery was commenced in the MDL Proceeding with respect to unaffiliated, non-NECC entities and individuals, including vendors, clinics, medical service providers, and distributors, not directly affiliated with NECC, that are alleged to have had some liability for the Outbreak. [MDL Dkt. No. 101].

2013); *MDL Order No.* 6 [MDL Dkt. No. 209] ("Formal discovery of NECC and the affiliated defendants shall remain temporarily stayed as set forth in this order and the previous orders of the Court."); *MDL Order No.* 7 [MDL Dkt. No. 438] (staying fact discovery of NECC and the NECC Affiliated Defendants "until further order of the Court"). <sup>11</sup>

32. As a result of the Trustee's settlement negotiations with the Insiders (undertaken with the participation of counsel to the Committee and Lead Counsel to the PSC), and aided by the discovery stay, the Trustee and the Committee announced on December 23, 2013 that settlements in principle had been reached with the Insiders, as well as with NECC's primary and excess insurers (collectively, the "Insider and Insurer Settlements"). These settlements will contribute over \$100 million to the NECC estate in the form of cash contributions from NECC's insiders, as well as proceeds from, among other things, NECC's related company's and individuals' professional liability insurance, tax refunds which will be due to the Insiders as a result of their cash settlement payments, and the sale of a related business. In exchange, the Insiders and NECC's insurers will receive releases from liability and injunctions in aid thereof, to be contained in the Plan. See Preliminary Settlement Agreements Establish \$100M Fund for Victims of Tainted Steroids Traced to NECC, Reuters (Dec. 23, 2013) (describing the preliminary agreements of NECC's insiders and insurers to contribute an amount exceeding \$100 million to "a compensation fund to be distributed to NECC creditors, including victims who received injections of tainted steroids traced to NECC"). 12

Notwithstanding the discovery stay, in order to facilitate the identification of potential third parties with liability in connection with the Outbreak and attempt to facilitate an early cost effective resolution of claims against them, the Trustee, through his specially retained counsel (Harris Beach PLLC), has provided informal discovery to the PSC and non-affiliated defendants through sixteen separate productions, encompassing over 5,900 documents and over 42,000 pages. The Trustee's counsel has responded expeditiously to each request by the PSC for additional documents, formulated and executed searches and expended significant time and resources to respond to such informal discovery requests.

available at http://www.reuters.com/article/2013/12/23/ma-necc-settlement-idUSnPnNEg2mBD+163+PRN20131223

33. Since these settlements in principle were reached, the Trustee and the Committee have been jointly, and in conjunction with the Insiders' and insurers' counsel, drafting and negotiating definitive documentation of the settlements. The agreements are complicated and in various respects interrelated, and many parties (and their attorneys), including creditor committee members' attorneys, are participating in reviewing, revising and finalizing the agreements. The Trustee and the Committee anticipate that final, executed settlement agreements will be completed shortly. Once finalized and executed, the settlement agreements will be presented to the Bankruptcy Court for approval; initially on a stand-alone basis and later as part of the comprehensive Plan containing the non-debtor releases, and injunctions in aid thereof, that are conditions to the settlement agreements' being consummated and the settlement monies' released to the NECC estate for delivery to the Claimants' Compensation Fund and subsequent distribution to injured claimants.

# B. The Mediation Program and Status of Mediations

- 34. In addition to contributions from the Insiders and NECC's insurers, the Chapter 11 Trustee's and the Committee's Chapter 11 Plan contemplates contributions from non-NECC affiliates, such as NECC's vendors and pain clinics and medical care providers that may be exposed to liability in connection with the Outbreak. Accordingly, in August 2013, the Trustee, the Committee and the PSC submitted to this Court proposed orders establishing mediation protocols with respect to those parties. See MDL Dkt. Nos. 374, 380, 388. On August 15, 2013, this Court entered an *Order on Mediation* [MDL Dkt. No. 394] (the "Mediation Order", attached hereto as **Exhibit E**), adopting some aspects of both the joint proposed order of the Trustee and Committee and the PSC's proposed order.
- 35. The Mediation Order established a program (the "Mediation Program") that will seek to resolve the claims of those parties other than the NECC Affiliated Defendants or Insiders

- (1) who have or may have claims asserted against them as defendants by personal-injury and wrongful-death plaintiffs that arise out of or relate to NECC products; and (2) who, as a result of claims or potential claims against them, have or may have indemnification, contribution, reimbursement or other claims against the NECC estate (the "Non-Affiliated Defendants"). See Mediation Order ¶ C.
- 36. On October 28, 2013, the Trustee, the Committee and the PSC jointly proposed that this Court appoint Resolutions, LLC ("Resolutions" or the "Mediator"), headed by Eric Green, Esq., as mediator under the Mediation Program. [MDL Dkt. No. 536]. On November 6, 2013, this Court entered an order approving the appointment. [MDL Dkt. No. 549].
- 37. Mediation is already well underway with respect to several Non-Affiliated Defendants, including NECC vendors and clinics and health care providers that administered injections of tainted NECC products and others. Specifically, the following entities are currently participating in the Mediation Program:
  - ARL BioPharma, d/b/a Analytical Research Laboratories (which provided product sample testing services to NECC);
  - Victory Mechanical Services, Inc. and the related entity Victory Heating & Air Conditioning Co., Inc. (which installed ventilation systems at NECC);
  - Liberty Industries, Inc. (which designed, manufactured, and installed the cleanrooms used to compound, mix and prepare, NECC's contaminated products);
  - Orlando Center for Outpatient Surgery, LP (a Florida clinic that administered tainted MPA); and
  - Pain Management Center of West Orange (a Florida pain management clinic that administered tainted MPA).

Additional parties are engaged in private mediation outside of the Mediation Program with approval of this Court, including Inspira Health Network, Inc. and Inspira Medical Centers, Inc.

(related New Jersey clinics that administered among the largest numbers of tainted MPA injections).

- 38. To date, the mediation parties, including representatives of the Trustee, the Committee, and the PSC, <sup>13</sup> have been engaged in productive preparation for mediation, including discussions between and among the parties and the Mediator, document production and information exchanges, analysis of the information and the exchange of position and mediation statements. In-person mediation sessions conducted by Professor Green and/or his colleague Carmin Reiss are scheduled to begin during the first week of April 2014. The Trustee and the Committee expect that successful mediations will result in contributions of additional sums to the NECC estate for delivery, post-Plan confirmation, to the Claimants' Compensation Fund, in exchange for injunctions and releases from liability to be included in and provided by the Plan.
- 39. The Trustee and the Committee are hopeful that additional clinics, vendors, and health care providers will choose to participate in the Mediation Program and to take advantage of the injunctions and releases from liability not otherwise available to them absent their participation. However, given that the Trustee and the Committee hope to submit and confirm the Plan within the calendar year, the window of time in which these potentially liable parties must elect to participate in the Mediation Program is rapidly closing.

## C. Transfer of Personal Injury and Wrongful Death Cases to this Court

40. In order to promote the orderly administration of claims related to the tainted MPA, and to facilitate the Plan and the mediations that would result in further contributions to the NECC estate, on March 10, 2013, the Trustee filed in this Court a *Motion to Transfer Personal Injury Tort and Wrongful Death Cases to this Court pursuant to 28 U.S.C.§§ 1334 and* 

A schedule of mediation parties, including the names of the representatives of the Trustee, the Committee, and the PSC, is attached hereto as **Exhibit F**.

157(b)(5) [MDL Dkt. No. 37] (the "<u>Transfer Motion</u>"). The Transfer Motion sought to transfer to the MDL, pursuant to 28 U.S.C. § 157(b)(5), of all personal injury and wrongful death cases then pending in both state and federal courts which involved claims arising from use of allegedly contaminated pharmaceuticals compounded and/or distributed by NECC and other third parties. As this Court observed in its *Memorandum and Order on Trustee's Motion to Transfer*, dated May 31, 2013 [MDL Dkt. No. 170] (the "<u>Transfer Opinion</u>"), the Transfer Motion sought the transfer of cases which fall into the four (4) following categories:

(1) cases pending in other federal courts that have not yet been transferred here; (2) cases pending in state courts where removal is in process; (3) cases pending in state courts that name NECC or affiliated entities as defendants; and (4) cases pending in state courts that do not name NECC or affiliated entities as defendants.

In re New Eng. Compounding Pharm. Prods. Liab. Litig., 496 B.R. 256, 262 (D. Mass. 2013).

41. The Transfer Motion was granted by this Court on May 31, 2013 as to those cases within categories (1), (2) and (3). The Transfer Motion was denied, without prejudice, as to cases within category (4). <u>Id.</u> at 277-78. With regard to category (4) cases, this Court assumed the existence of subject matter jurisdiction, but declined to exercise its discretion and abstained from exercising such jurisdiction. <u>Id.</u> at 277. This Court held:

The transfer of some, but not all, state-court cases might be something of a pointless exercise if the possibility remains that a state-court defendant could make a future claim in the bankruptcy case for contribution or indemnity, upsetting the effort to make an equitable distribution to the victims and other creditors. Indeed, that is the essential basis of the trustee's motion: that the Court must transfer all state-court cases to foreclose that very possibility.

The Court is not convinced, at least at this stage, that such a step is necessary. Other possible courses of action might produce the desired consolidation and finality, without resolving difficult issues of jurisdiction and abstention and without intruding unnecessarily into the proceedings of state courts. For example, if the Bankruptcy Court were to set a relatively early bar date for the filing of claims against the estate, it would appear that any

defendant in a state-court action would be effectively forced to decide whether it wanted to file a claim for contribution or indemnity against the estate. Such a claim, in turn, would probably permit the exercise of federal jurisdiction over the underlying matter. Any defendant who did not file a claim would be barred, and the state-court case could proceed to judgment without interference from the federal court. Either way, the desired goals would be achieved with a relatively minimal degree of risk or intrusion.

In any event, the Court does not need to reach the issue at this juncture. If the balance of factors shifts over time, the Court can revisit the issue, and if necessary (and appropriate) can issue further orders concerning the exercise of related-to jurisdiction.

<u>Id.</u> at 269-70.

42. With respect to state court actions involving potential indemnification claims against the NECC estate, this Court noted that

[i]f the Court were to decline to assert jurisdiction over the state-court cases, it might make it difficult or impossible to resolve the entire litigation in an equitable or efficient manner. Any cases that remain pending in state court could ultimately result in large judgments and corresponding claims for contribution or indemnity against the estate of NECC.

Id. at 263.

43. This Court further explained that any such claims, in turn, would pose serious dangers to victims' recoveries:

[p]ursuant to the bankruptcy code, such claims would normally have to be considered on equal footing with the claims of injured plaintiffs against the estate as claims of unsecured creditors. Because all unsecured creditors are normally paid *pari passu* (that is, proportionally and without preference) based on the amount of their claims, even one large contribution or indemnity claim against the estate could greatly diminish, or virtually eliminate, the amount available to be paid to the remaining claimants.

<u>Id.</u>

44. Finally, this Court recognized that "allowing some state-court cases to proceed without consolidation in the MDL creates the possibility of inconsistent rulings or judgments on factual or scientific issues that may greatly complicate the resolution of these matters" and that "litigation in multiple courts also threatens to impose significant discovery burdens, as discovery from many of the same people and entities may be sought on multiple occasions." <u>Id.</u> at 263-44. This Court concluded that "the most efficient use of the limited resources of the judicial system, and the fairest and most efficient distribution of the assets of the estate, would be for all of the related cases to be consolidated in one court. Abstention would be counterproductive to that end." <u>Id.</u> at 273.

## III. PENDING MATTERS

45. As of the date of Judge Saylor's recusal, three significant matters remained pending before this Court: (i) the Trustee's renewed motion to transfer certain state court actions to this Court (which the Committee supports); (ii) the PSC's motion to lift the discovery stay with respect to the NECC Affiliated Defendants (which the Trustee and the Committee oppose) and (iii) the PSC's motion to establish a "common benefit fund" for the benefit of attorneys litigating in the MDL Proceeding (which the Trustee and the Committee oppose on a limited basis). Given the importance of these matters, the Trustee and the Committee respectfully request that the Renewed Transfer Motion, the Lift Stay Motion, and the Common Benefit Fund Motion (each as defined below) be heard at the status conference scheduled for March 13, 2014, so that they may be resolved promptly.

#### A. The Trustee's Renewed Transfer Motion

46. On December 20, 2013, Insight Health Corp. ("<u>Insight</u>"), a defendant in twenty-two (22) personal injury and wrongful death cases pending in Virginia state court (the "<u>State Court Actions</u>"), see *Statement of Insight Health Corp. (A) in Support of Chapter 11 Trustee's* 

Renewed and Supplemental Motion to Transfer Additional Personal Injury Tort and Wrongful Death Cases to this Court Pursuant to 28 U.S.C. §§ 157(b)(5) and 1334 (Docket No. 732) and (B) in Response to Oppositions to Same (Docket Nos. 764, 766, 792, 799) [MDL Dkt. No. 820] at 1, asserted claims against NECC for indemnity and contribution in a proof of claim filed in the Chapter 11 Case. See Proof of Claim No. 323, as amended by Proof of Claim No. 561 (the "Insight Proof of Claim", attached hereto as **Exhibit G**). The Insight Proof of Claim seeks indemnity or contribution in an amount which may allegedly exceed \$100 million.

### 47. As the PSC has noted,

the Insight claim is no ordinary proof of claim; it seeks potentially massive recovery in circumstances of a highly limited fund. In these truly unique circumstances, the Insight claim can theoretically have an overwhelming effect on the claims of all victims nationwide.

Plaintiffs' Steering Committee's Response to the Chapter 11 Trustee's Renewed Motion to Transfer [MDL Dkt. No. 789] at 8-9. Moreover, the plaintiffs in the Virginia State Court Actions subsequently filed proofs of claim, which provide an additional basis for this Court's jurisdiction over the State Court Actions. In accordance with the Transfer Opinion, the Trustee has therefore filed a renewed and supplemental motion in support of an Order transferring the State Court Actions (the "Renewed Transfer Motion") to this Court. [MDL Dkt. No. 732]. The Committee, in turn, has filed a joinder to the Renewed Transfer Motion. [MDL Dkt. No. 743].

48. For the reasons cited in the Transfer Opinion, allowing the State Court Cases to proceed to judgment in state court would seriously interfere with the "carefully crafted system for the orderly administration" of NECC's estate. 496 B.R. at 272. The Renewed Transfer Motion, which is fully briefed, remains pending before this Court. Judge Saylor was to hear argument on the Renewed Transfer Motion at the February 6, 2014 status conference, when he instead announced his recusal.

# B. The PSC's Motion to Lift Discovery Stay

- 49. On October 28, 2013, the PSC filed a motion to lift the discovery stay with respect to the NECC Affiliated Defendants and Insiders: *i.e.*, Ameridose, LLC, Medical Sales Management, Inc., Barry J. Cadden, Gregory Conigliaro, Lisa Conigliaro Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn A. Chin, GDC Properties Management, LLC, and Medical Sales Management SW, Inc. [MDL Dkt No. 534] (the "<u>Lift Stay Motion</u>"). The PSC argued that lifting the stay was appropriate because, as of late October, there were no settlements or other resolutions with any of these parties.
- Defendants, the Insiders and their insurers, and the likelihood that the time-intensive and expensive process of formal discovery would divert resources and attention from and frustrate the finalizations of those settlements, the Trustee opposed, and continues to oppose, the Lift Stay Motion. See Memorandum of Law of Chapter 11 Trustee in Response to Plaintiffs' Steering Committee's Motion to Partially Lift Discovery Stay [Dkt. No. 757]. The Committee has likewise opposed the Lift Stay Motion, and filed a Joinder to the Trustee's opposition [Dkt. No. 762]. The Committee has
- 51. At the February 6, 2014 status conference, Judge Saylor determined that the discovery stay would remain in place and the Lift Stay Motion would remain pending.

Moreover, once the settlement agreements are finalized, the scope of necessary discovery is likely to be significantly narrowed, thereby permitting more tailored discovery that will conserve the resources of the estate.

In the alternative, the Committee requested that this Court adjourn consideration of the Lift Stay Motion to a later status conference date in order to provide the parties sufficient time to finalize and execute full settlement agreements.

## C. The PSC's Common Benefit Fund Motion

- 52. On January 17, 2014, the PSC moved to establish a common benefit fund that would be funded by an eight percent (8%) tax on recoveries intended for plaintiffs, including recoveries realized through "any settlement related to any bankruptcy proceedings." See Plaintiffs' Steering Committee's Motion for Entry of Case Management Order Establishing Assessment Procedures to Fund Common Benefit Account [MDL Dkt. No. 790] (the "Common Benefit Fund Motion").
- 53. The Trustee and the Committee oppose this procedure to the extent it contemplates an assessment on the proceeds of the Insider and Insurer Settlements or the proceeds of any additional settlements the Trustee and the Committee anticipate will be negotiated with other parties, through mediation or otherwise, which proceeds constitute property of NECC's bankruptcy estate under the Bankruptcy Code. See Limited Objection of the Official Committee of Unsecured Creditors to Plaintiffs' Steering Committee's Motion for Entry of Case Management Order Establishing Assessment Procedures to Fund Common Benefit Account [MDL Dkt. No. 833]; Limited Objection of Chapter 11 Trustee of New England Compounding Pharmacy, Inc. to Plaintiffs' Steering Committee's Motion for Entry of Case Management Order Establishing Assessment Procedures to Fund Common Benefit Account [MDL Dkt. No. 834]. Individual Committee member representatives also opposed the Common Benefit Fund Motion. See Response to Plaintiffs' Steering Committee's Motion for

The Committee further notes that the Common Benefit Fund Motion and accompanying proposed order do not expressly incorporate a June 6, 2013 letter between Lead Counsel to the PSC and the Committee agreement regarding, *inter alia*, the establishment of a common benefit fund, which agreement provided that "Common Fund participants may include member representatives serving on the Official Committee, to the extent the services they perform are for the common benefit of multiple tort victims." See Limited Objection of the Official Committee of Unsecured Creditors to Plaintiffs' Steering Committee's Motion for Entry of Case Management Order Establishing Assessment Procedures to Fund Common Benefit Account [MDL Dkt. No. 833] ¶ 8, Ex. A (letter agreement). The Common Benefit Fund Motion and accompanying proposed order do not contemplate the Committee members' representatives' participation in any distributions from the common benefit fund.

Entry of Case Management Order Establishing Assessment Procedures to Fund Common Benefit Account and Amended Proposed Orders [MDL Dkt. No. 830].

54. In response to the Trustee's and the Committee's Limited Objections, the PSC has proposed three possible procedural methods through which this Court might accomplish the sequestration of common benefit funds:

First, the Court could require that a percentage of the funds to be paid into the bankruptcy estate pursuant to any settlement with NECC Affiliated Defendants (or others) be set aside in a common benefit fund [("Option 1")]. Second, the Court could require the claims of attorneys in the MDL who are or may become entitled to payment of fees from a common benefit fund be recognized as a valid claim in the bankruptcy proceedings itself and paid in due course into a common benefit account [("Option 2")]. The final possibility is that if there is a tort trust created as part of an approved bankruptcy plan, the Court require that a percentage of those funds be set aside and paid into a common benefit account for later distribution [("Option 3")].

See Plaintiffs' Steering Committee's Reply in Support of Motion for Entry of Common Benefit Order [Dkt. No. 873] at 4-5 (the "CBF Reply").

55. Judge Saylor was to hear argument on the Common Benefit Fund Motion at the status conference held before this Court on February 6, 2014. However, given his recusal, no substantive matters were heard on that date, and the Trustee and the Committee were granted leave to file sur-replies, or a joint sur-reply, to the CBF Reply. In their sur-reply, see MDL Dkt. No. 914, the Trustee and the Committee submitted that both Option 1 and Option 2 would interfere with property of NECC's estate, and thus that neither resolves the central issue raised in the Trustee's and the Committee's Limited Objections, *i.e.*, that *any* attempt to interfere with property of the estate, including through a direct tax on settlement funds (Option 1) or through this Court's preemptively allowing "valid claim[s]" against the estate (Option 2), is improper. See <u>id.</u> ¶ 4. The Trustee and Committee further submitted that of the common benefit fund assessment Options presented by the PSC, only Option 3—waiting until a post-petition tort trust

is funded, and seeking to apply an assessment to the funds in that trust—does not directly implicate the issues raised in the Trustee's and the Committee's Limited Objections. See id. ¶ 5. That said, neither the Trustee nor the Committee has taken a position on whether the Common Benefit Fund Motion should be granted or on whether Option 3 is an appropriate assessment mechanism.

56. As with the Renewed Transfer Motion, the Common Benefit Fund Motion has been fully briefed and remains pending before this Court.

### **CONCLUSION**

57. In sum, although these proceedings have a number of unique, complex, and interrelated issues, the prospect of a material resolution for the benefit of tort claimants and other creditors is rapidly solidifying. Between the Insider and Insurer Settlements and the ongoing mediations, there has been considerable progress made, with continued cooperation among all parties in both the MDL Proceeding and the Chapter 11 Case, as well an efficient coordination of the parallel proceedings pending in this Court and the Bankruptcy Court. The Trustee and the Committee are justifiably optimistic regarding the progress of these proceedings and the Chapter 11 Case and remain committed to, and focused on, achieving an expeditious and fair resolution of this proceeding and the Chapter 11 Case for the benefit of those who have incurred both personal and financial losses by reason of this tragic Outbreak.

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Dated: March 5, 2014

Respectfully submitted,

#### **DUANE MORRIS LLP**

/s/ Michael R. Gottfried Michael R. Gottfried, Esq. (BBO #542156) 100 High Street Suite 2400 Boston, MA 02110-1724

Telephone: (857) 488-4200 mrgottfried@duanemorris.com

Counsel for Paul D. Moore, Chapter 11 Trustee of New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center

#### HARRIS BEACH PLLC

/s/ Frederick H. Fern Frederick H. Fern, Esq. 100 Wall Street New York, NY 10005 Telephone: (212) 687-0100 hbnecc@harrisbeach.com

Specially Appointed Counsel to the Chapter 11 Trustee of New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center

#### **BROWN RUDNICK LLP**

By: /s/ David J. Molton David J. Molton, Esq. Seven Times Square New York, New York 10036 Telephone: (212) 209-4800 Facsimile: (212) 209-4801 dmolton@brownrudnick.com

and

William R. Baldiga, Esq. (BBO #542125) Kiersten A. Taylor, Esq. (BBO #681906) One Financial Center Boston, Massachusetts 02111 Telephone: (617) 856-8200 Facsimile: (617) 856-8201 wbaldiga@brownrudnick.com ktaylor@brownrudnick.com

Counsel to the Official Committee of Unsecured Creditors of New England Compounding Pharmacy, Inc.

# **CERTIFICATE OF SERVICE**

I, Carol S. Ennis, hereby certify that on March 5, 2014, I caused a copy of the foregoing Joint Status Report to be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants, by first class mail, postage prepaid.

Dated: March 5, 2014

Boston, Massachusetts

/s/ Carol S. Ennis Carol S. Ennis

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